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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,814

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Isao Sakata

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EXAMINER

JAVANMARD, SAHAR

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,814	SAKATA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 7-8, and 13-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 2/26/08.
Claim(s) 1-2, 7-8, and 13-14 are pending. Claim(s) 3-6, 9-12 and 15-18 have been cancelled. Claim(s) 1-2, 7-8, and 13-14 are examined herein.

Response to Arguments

Applicant's amendments have rendered the ODP rejection as it applies to claims 3-6, 9-12, and 15-18 moot, and is hereby withdrawn.

Applicant's amendments have rendered the 112 2nd rejection of claims 1-18 moot, and is hereby withdrawn.

Applicant's amendments have rendered the 101 rejection of claims 5, 6, 11, 12, 17, and 18 moot, and is hereby withdrawn.

Applicant's amendments have rendered the 102(b) rejection of claims 3-6, 9-12 and 15-18 over Hiked a (US Patent No. 6,063,777) moot and the rejection is hereby withdrawn. Further, Examiner inadvertently included claims 1-2, 7-8 and 13-14 in the 102(b) rejection over Hiked a (US Patent No. 6,063,777) and the rejection is hereby withdrawn.

Applicant's amendments have rendered the 103 rejection of claims 3-6, 9-12 and 15-18 over Hiked a (US Patent No. 6,063,777) in view of Levy (Trends Biotechnology, 1995) moot and the rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) obviousness rejection of claims 1-18 over Hikida et al US Patent No. 6,063,777 in view of Levy (Trends Biotechnology, 1995) has been fully considered but is found to be not persuasive as Applicant is now arguing based on amended claims. In view of applicants amendments and cancellation of some claims the following modified 35 USC 103 (a) rejections are being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777).

Hikida teaches an iminochlorine aspartic acid derivative of the compound of formula I and pharmaceutically acceptable salts thereof (abstract, column 1, lines 8-10), in particular the sodium salt (column 6, lines 56-59)

Hikida further teaches that the iminochlorine aspartic acid derivative of the compound of formula I, a photosensitizer molecule, is administered in photodynamic therapy (PDT) as a new method for the treatment of cancer. The porphyrin derivative is taken up by the cancerous tissues in the subject, which is then followed by laser radiation causing selective destruction of the cancerous tissues (column 1, lines 15-26). Additionally, Hikida teaches that the use of this compound in PDT is extremely useful as a diagnostic agent for cancers and ophthalmic neurovascularization (column 13, lines 4-6, and the claims).

Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative of the compound of formula I for determining the location of a sentinel lymph node and the presence of cancer metastasis by PDT.

It would have been obvious to one of ordinary skill in the art to have employed the iminochlorine aspartic acid derivative of the compound of formula I as taught by Hikida and used them to determine the location of a sentinel lymph node and the presence of cancer metastasis by PDT. One would be motivated to employ said compounds because Hikida teaches that these compounds are extremely useful as

diagnostic agents. Thus one would expect with a reasonable degree of certainty that the administration of said compounds would be successful in detecting the sentinel lymph node and as a result detecting the presence of metastasis.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) as applied to claims 13 and 14 above in view of Levy (Trends Biotechnology, 1995).

Hikida is discussed above.

Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative of the compound of formula I for the treatments of rheumatoid arthritis and inflammatory keratosis.

Levy teaches that the photosensitizer molecules that have been used both clinically and experimentally in PDT tend to accumulate selectively and be retained by abnormal or hyperproliferative cells, particularly those fed by neovasculature, such as cancer tissue (page 14, column 1, lines 16-20).

Levy further teaches that most photosensitizers currently being investigated in clinical studies exert their effect on tumors by their selective accumulation in both rapidly dividing or activated cells and neovasculature, any disease in which the underlying pathology involves these characteristics is a potential candidate for PDT (page 14, column 2, lines 10-19). Table 1 gives a partial list of such diseases and

includes only those conditions for which there is some evidence, either clinical or preclinical, that PDT may have efficacy (page 16). These include psoriasis (i.e., inflammatory keratosis), macular degeneration of the retina, autoimmune conditions (i.e. rheumatoid arthritis), atherosclerosis and restenosis (page 16, lines 11-18). This apparently disparate group of diseases has common underlying features in their pathology, which provide a common ground for treatment with PDT.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have applied the iminochlorine aspartic acid derivative of the compound of formula I as taught by Hikida for methods of treating the diseases as taught by Levy.

One would be motivated to employ the iminochlorine aspartic acid derivative taught by Hikida to treat the ailments taught by Levy because the compounds taught in both references, though different, are used to both detect and treat cancer in addition to being photosensitizers. Both references teach their respective compounds as having the potential of being useful in PDT. Thus one would expect with a reasonable degree of success that a photosensitizing compound such as the iminochlorine aspartic acid derivatives taught by Hikida that can diagnose and treat cancer can also be employed to treat the ailments taught by Levy, one of which is cancer.

Furthermore, because of its quick metabolism in a living body, PDT exhibits no toxicity against abnormal cells and would increase patient compliance as a result.

Conclusion

Claims 1-2, 7-8, and 13-14 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617